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60/306,652 **18 July 2001 (18.07.2001)** **US**
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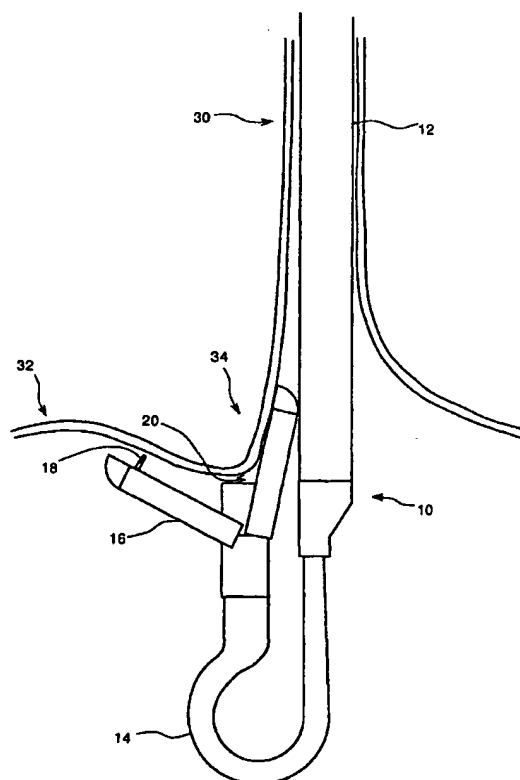
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[Continued on next page]

(54) Title: **METHODS AND DEVICES FOR TISSUE RECONFIGURATION**



(57) Abstract: A method includes advancing an apparatus (10) including an elongated member (12) transorally into the stomach. The apparatus (10) includes a distal end effector (15) having first and second members (16) configured to engage tissue. The first and second members (16) are movable relatively toward one another generally in a first plane. The method includes moving the distal end effector relative to the elongated member (12) in the first plane such that the distal end effector is retroflexed out of alignment with the elongated member (16) to position the first and second members (16) for engagement with the tissue. At least one of the first and second members (16) carries a fixation device (22) for fixing engaged portions of tissue together.

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METHODS AND DEVICES FOR TISSUE RECONFIGURATION

BACKGROUND OF THE INVENTION

Brief Description of the Related Art

5 This invention relates to devices and methods for treating gastroesophageal reflux disease, and more particularly, the invention relates to a minimally invasive device and method for creating and fixating a fold of tissue at or near the junction of the esophagus and the stomach.

 Gastroesophageal reflux disease (GERD) is a common upper-intestinal
10 disorder in which contents of the stomach flow inappropriately from the stomach into the esophagus. Backflow of gastric contents into the esophagus results when gastric pressure is sufficient to overcome the resistance to flow that normally exists at the gastroesophageal junction (GEJ), or when gravity acting on the contents is sufficient to cause flow through the GEJ. Medication, open surgical procedures, laparoscopic
15 surgical procedures, and endoscopic techniques are known for treating GERD.

SUMMARY OF THE INVENTION

 According to one aspect of the invention, a medical instrument includes moveable arms configured for fixating the wall of the stomach to the wall of the esophagus for the treatment of GERD. In one embodiment, the instrument includes a
20 proximal end, a shaft, a retroflexing portion, movable arms, a retractor, and an implant. The movable arms are oriented with respect to the retroflexing portion in a position that allows the stomach wall to be folded against the esophagus wall. In one such embodiment of this instrument the movable arms open and close in the same plane within which the retroflexing portion moves. This configuration is in contrast
25 to certain embodiments of medical instruments described in International Publication Number WO 00/78227 A1 entitled "GERD TREATMENT APPARATUS AND METHOD," published December 28, 2000, and United States publication number 20020040226A1 entitled "TISSUE RECONFIGURATION," published April 4, 2002, in which moveable arms are oriented in a plane rotated 90° from the plane in which a

retroflexing portion moves. The mechanism of operation of the medical instrument of the current invention is as is disclosed in the referenced International Publication Number WO 00/78227 A1 and US publication number 20020040226A1.

According to another aspect of the invention, a method of treatment includes
5 fixating the wall of the stomach to the wall of the esophagus for the treatment of GERD.

According to another aspect of the invention, a method includes advancing an apparatus having an elongated member transorally into the stomach. The apparatus includes a distal end effector having first and second members configured to engage
10 tissue. The first and second members are movable relatively toward one another generally in a first plane. The method includes moving the distal end effector relative to the elongated member in the first plane such that the distal end effector is retroflexed out of alignment with the elongated member to position the first and second members for engagement with the tissue. At least one of the first and second
15 members carries a fixation device for fixing engaged portions of tissue together.

Embodiments of this aspect of the invention may include one or more of the following features. The method includes engaging tissue by moving the first and second members relatively toward one another generally in the first plane. Moving the first and second members engages a first tissue section with a first securing part of
20 the fixation device and a second tissue section with a second securing part of the fixation device. The method includes piercing the tissue with a third member of the distal end effector prior to engaging the tissue with the first and second members. The method includes moving the plane in which the first and second members are movable

25 **BRIEF DESCRIPTION OF THE DRAWINGS**

The invention will now be described in greater detail with reference to the preferred embodiment illustrated in the accompanying drawings, in which like elements bear like reference numerals, and wherein:

FIG. 1 is a side cross sectional view of a portion of an esophagus and a portion
30 of a stomach, and a side view of an instrument in place in the esophagus and stomach;

FIG. 2 is a side cross sectional view of a portion of the esophagus and a portion of the stomach, and a side view of the instrument in place in the esophagus and stomach, showing the instrument in a retroflexed position;

FIG. 3 is a side cross sectional view of a portion of the esophagus and a portion of the stomach, and a side view of the instrument in place in the esophagus and stomach, showing the movable arms open;

FIG. 4 is a side cross sectional view of a portion of the esophagus and a portion of the stomach, and a side view of the instrument in place in the esophagus and stomach, showing a retractor engaging tissue;

FIG. 5 is a side cross sectional view of a portion of the esophagus and a portion of the stomach, and a side view of the instrument in place in the esophagus and stomach, showing the retractor retracting the tissue;

FIG. 6 is a side cross sectional view of a portion of the esophagus and a portion of the stomach, and a side view of the instrument in place in the esophagus and stomach, showing the movable arms closed, forming a tissue fold;

FIG. 7 is a side cross sectional view of a portion of the esophagus and a portion of the stomach, and a side view of the instrument in place in the esophagus and stomach, showing the movable arms open and an implant fixating the tissue fold;

FIG. 8 is a side cross sectional view of a portion of the esophagus and a portion of the stomach, and a side view of the instrument in place in the esophagus and stomach, showing the tissue fold, with the instrument in a straight configuration for removal from the patient.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The device consists of an instrument 10 with a proximal end (not shown), a shaft 12, a retroflexing portion 14, and a distal end effector 15 including movable arms 16, a retractor 20, and an implant 22. The function of the instrument is controlled by the user by controls at the proximal end, as is disclosed in the referenced publications. The device and method of the present invention will be illustrated using the accompanying drawings.

FIG. 1 shows the instrument 10 in place in the esophagus 30 and the stomach 32. The instrument is in a straight configuration, which is the configuration in which it is inserted into the esophagus and stomach

FIG. 2 shows the instrument 10 in place in the esophagus 30 and the stomach 32, with the instrument 10 in a retroflexed position. Retroflexion of retroflexing portion 14 is accomplished as disclosed in the referenced publications. In this position, the distal end of the movable arms 16 of distal end effector 15 is located near the junction 34 of the esophagus 30 and the stomach 32.

FIG. 3 shows the instrument 10 in place in the esophagus 30 and the stomach 32, with the instrument 10 in a retroflexed position and the movable arms 16 in an open position revealing a portion 18 of an implant 22 (FIG. 7). It is important to note that the moveable arms 16 are oriented relative to the retroflexing portion 14 to grasp the tissue at the junction 34 of the esophagus 30 and the stomach 32. The movable arms 16 open and close in the same plane within which the retroflexing portion 14 moves. The actuating mechanism used to open movable arms 16 is substantially the same as the mechanisms used to actuate the medical instruments described in the US publication number 20020040226A1, entitled "TISSUE RECONFIGURATION," with the movable arms rotated 90° with respect to the configuration of the published application such that the arms 16 open and close in the same plane within which the retroflexing portion 14 moves.

FIG. 4 shows the instrument 10 in place in the esophagus 30 and the stomach 32, with the instrument 10 in a retroflexed position, the movable arms 16 in an open position, and the retractor 20 engaged with the tissue at or near the junction 34 of the esophagus 30 and the stomach 32. Engagement of the retractor 20 with the tissue at or near the junction 34 is accomplished as is disclosed in the referenced publications.

FIG. 5 shows the instrument 10 in place in the esophagus 30 and the stomach 32, with the instrument 10 in a retroflexed position, the movable arms 16 in an open position, and the retractor 20 retracting the tissue at or near the junction 34 of the esophagus 30 and the stomach 32 into the space between the movable arms 16.

FIG. 6 shows the instrument 10 in place in the esophagus 30 and the stomach 32, with the instrument 10 in a retroflexed position, and the movable arms 16 closed, to create a fold 36 of tissue at or near the junction 34 of the esophagus 30 and the stomach 32. The mechanism to close movable arms is as is disclosed in the
5 referenced publications.

FIG. 7 shows the instrument 10 in place in the esophagus 30 and the stomach 32, with the instrument 10 in a retroflexed position, and the movable arms 16 opened. An implant 22 has been placed through the tissue to maintain fixation of the tissue fold 36. Placement of the implant is accomplished as is disclosed in the referenced
10 publications.

FIG. 8 shows the instrument 10 in place in the esophagus 30 and the stomach 32, with the instrument 10 in a straight position, and the movable arms 16 closed. The tissue fold 36 is shown, fixated by implant 22. The instrument 10 is in position for removal from the patient.

15 This invention provides a device and method which can be used to treat GERD by creating and fixating a fold of tissue at or near the junction of the esophagus and the stomach, thereby fixating the wall of the stomach to the wall of the esophagus. This invention allows this fold to be created and fixated via a completely endoluminal technique.

20 In another aspect of the invention, more than one fold is created in the tissue at or near the junction of the esophagus and the stomach.

In another aspect of the invention, the movable arms are attached to the retroflexing portion in a manner that allows the operator to rotate the position of the movable arms relative to the retroflexing portion about the center axis of the movable
25 arms, thus allowing the operator to vary the orientation of the tissue fold.

While the invention has been described in detail with reference to the preferred embodiments thereof, it will be apparent to one skilled in the art that various changes and modifications can be made and equivalents employed, without departing from the present invention. For example, in the embodiment described above in
30 conjunction with FIGS. 1-8, the moveable arms open and close in the same plane

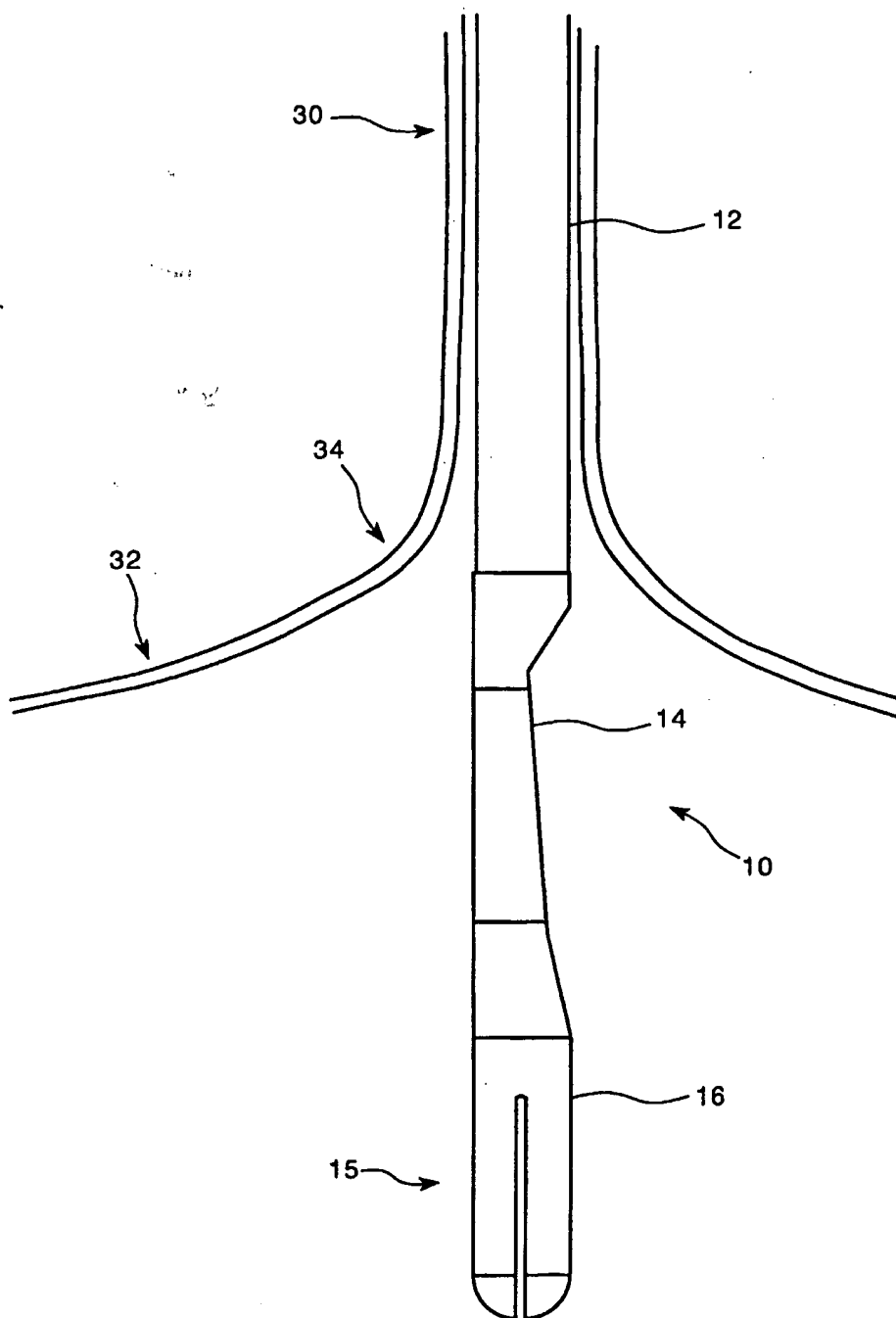
within which the retroflexing portion moves. However, it is appreciated that the plane in which the moveable arms open and close relative to the retroflexing portion can be at other orientations including angles between the same plane (i.e., 0°) and a plane transverse (i.e., 90°) to the plane within which the retroflexing portion moves. Indeed, 5 in certain embodiments, the medical instrument can include a mechanism for allowing the user to adjust the angle of the moveable arms relative to the retroflexing portion.

WHAT IS CLAIMED IS:

1. A method comprising:
advancing an apparatus including an elongated member transorally into the stomach, the apparatus including a distal end effector having first and second
5 members configured to engage tissue, the first and second members being movable relatively toward one another generally in a first plane, and
moving the distal end effector relative to the elongated member in the first plane such that the distal end effector is retroflexed out of alignment with the elongated member to position the first and second members for engagement with the
10 tissue, at least one of the first and second members carrying a fixation device for fixing engaged portions of tissue together.
2. The method of claim 1 further comprising engaging tissue by moving the first and second members relatively toward one another generally in the first plane.
- 15 3. The method of claim 2 wherein the moving of the first and second members engages a first tissue section with a first securing part of the fixation device and a second tissue section with a second securing part of the fixation device.
4. The method of claim 1 further comprising piercing the tissue with a third member of the distal end effector prior to engaging the tissue with the first and
20 second members.
5. The method of claim 1 further comprising moving the plane in which the first and second members are movable.

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FIG. 1



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FIG. 2

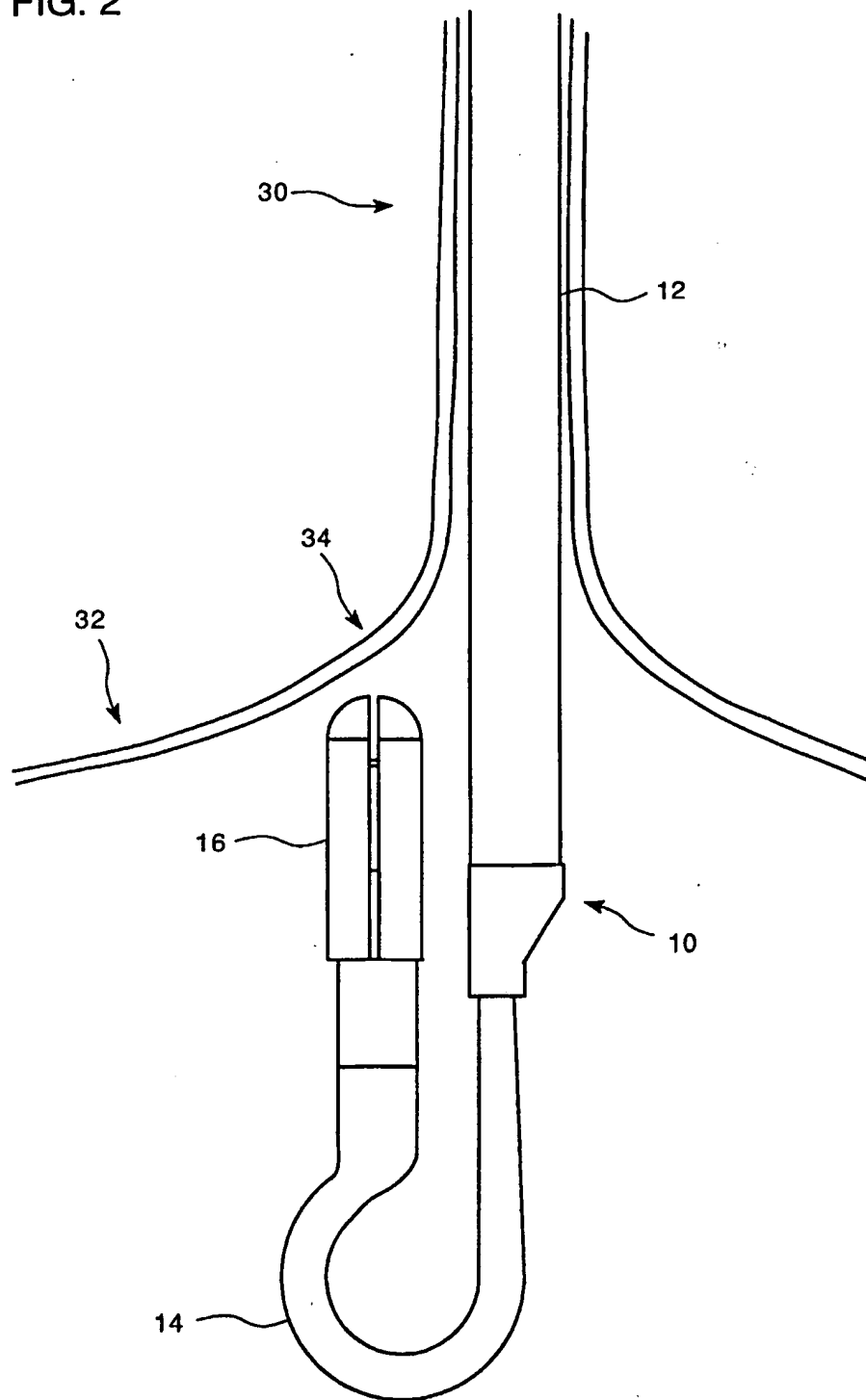


FIG. 3

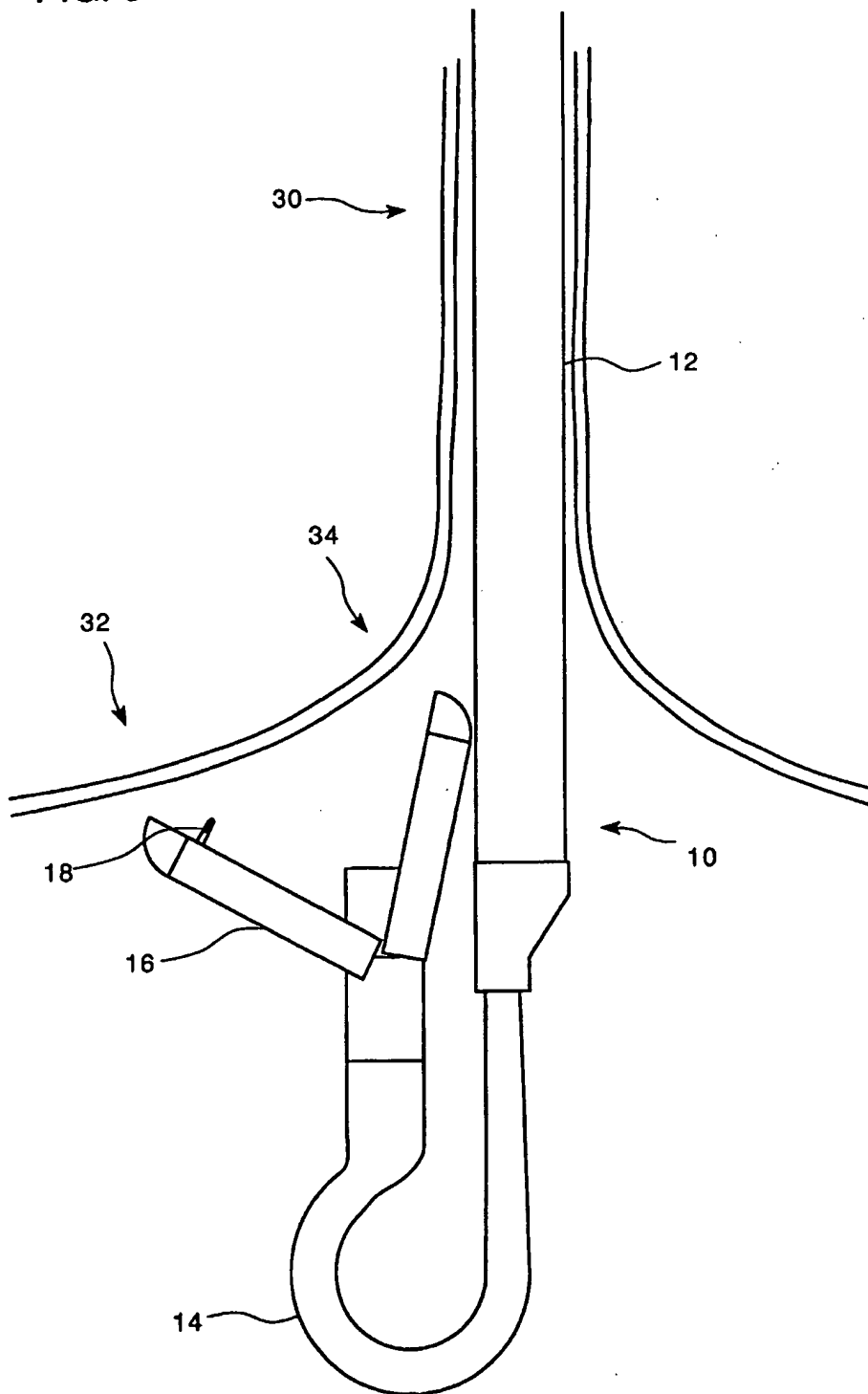
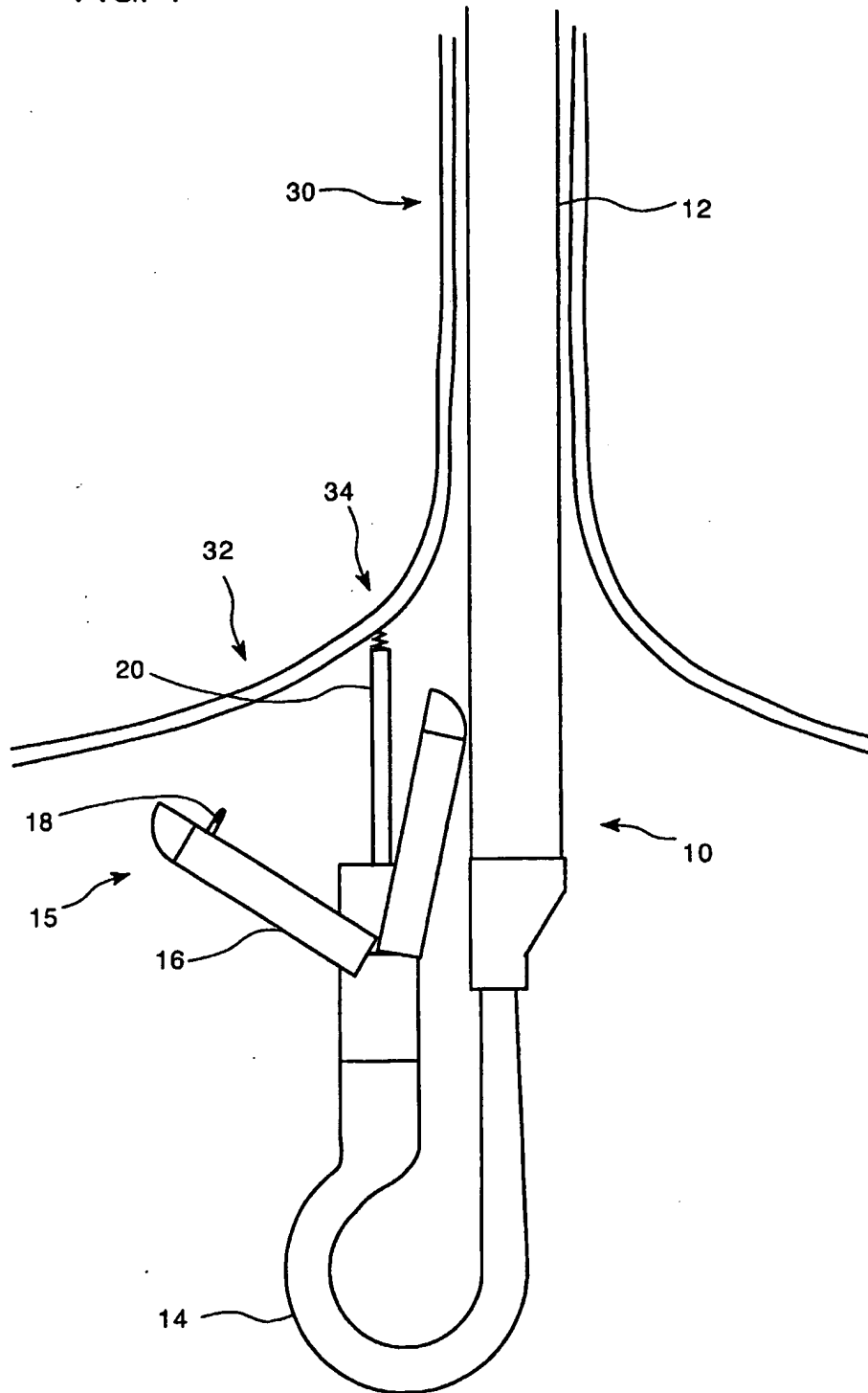
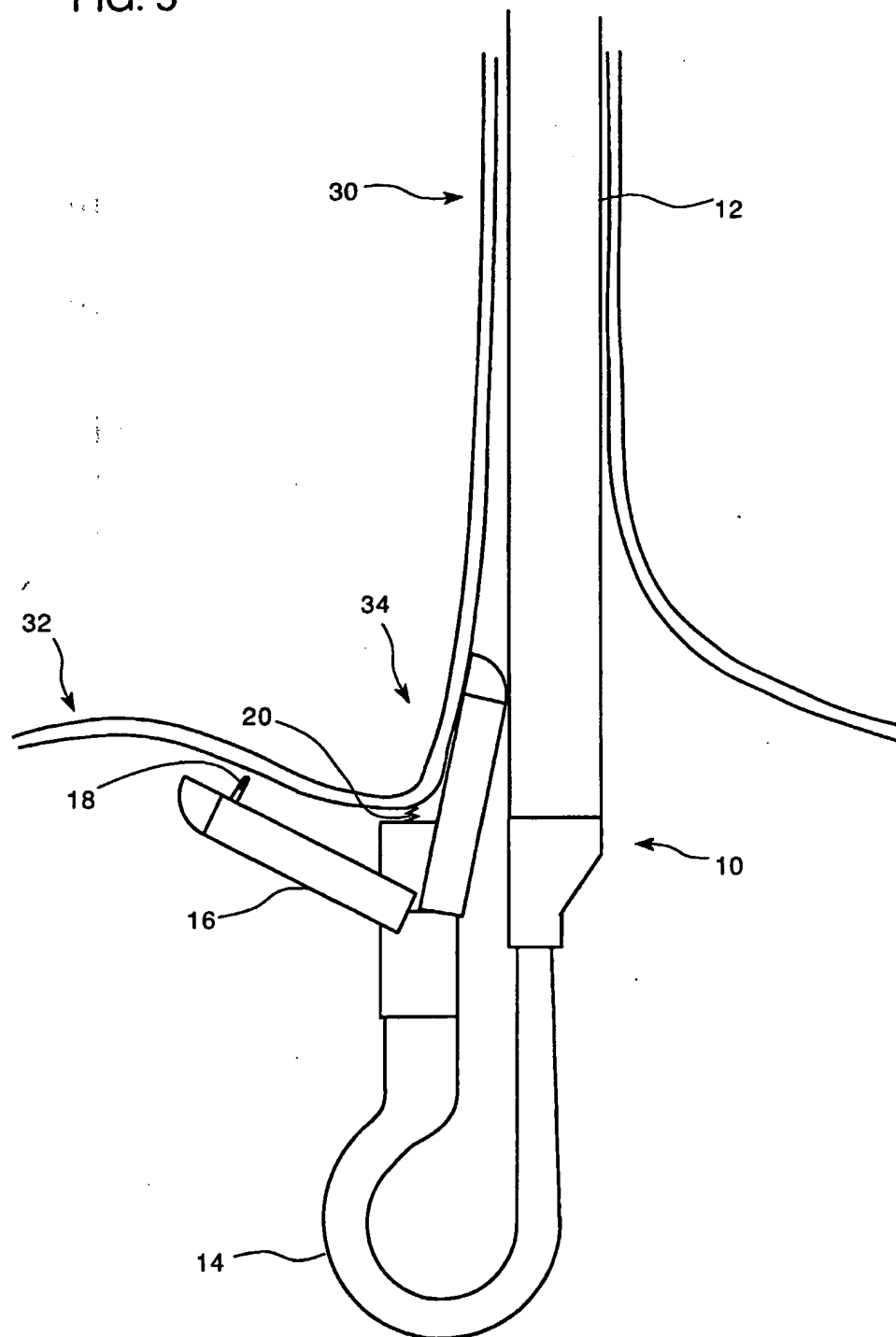


FIG. 4



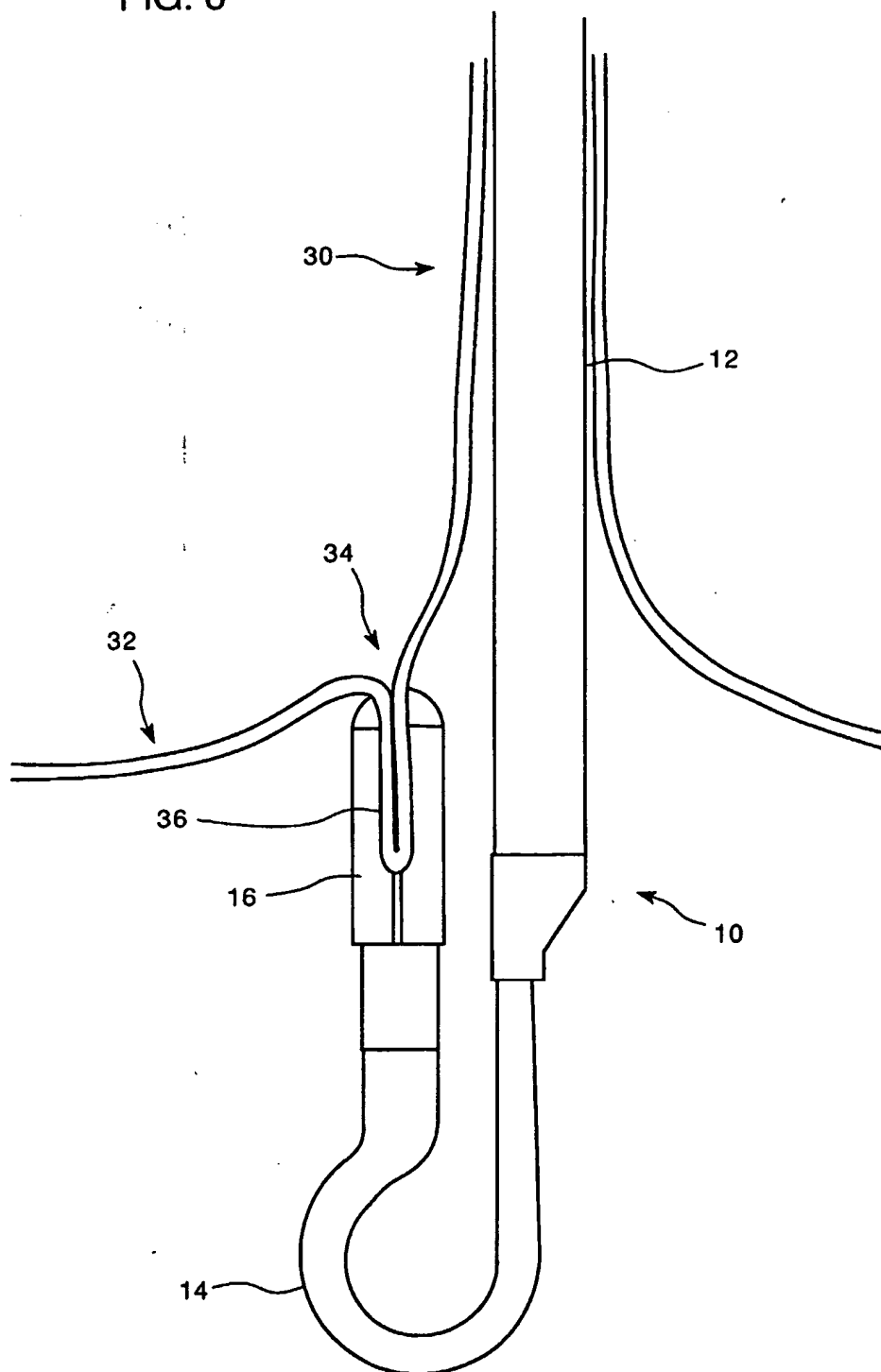
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FIG. 5



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FIG. 6



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FIG. 7

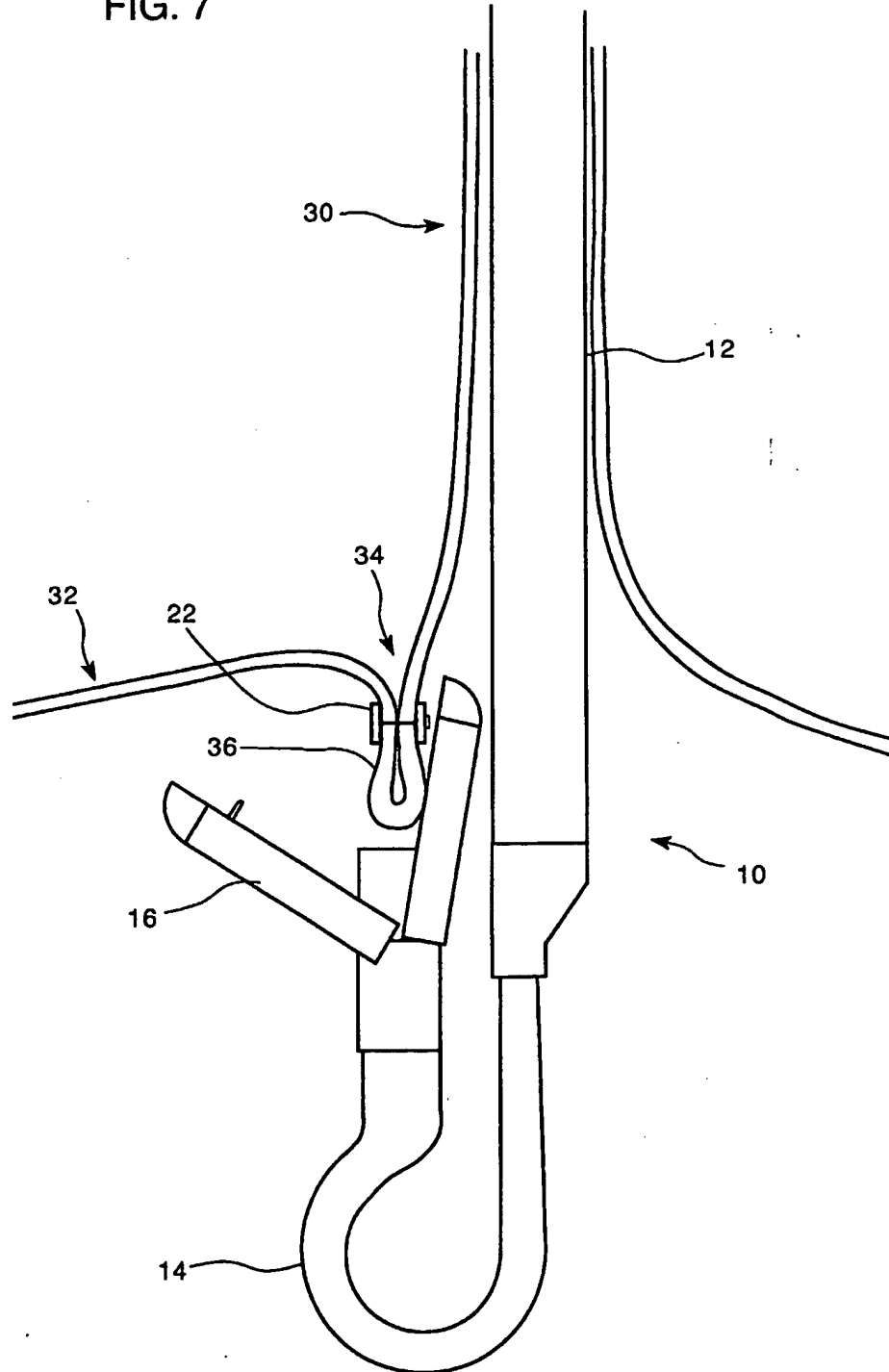
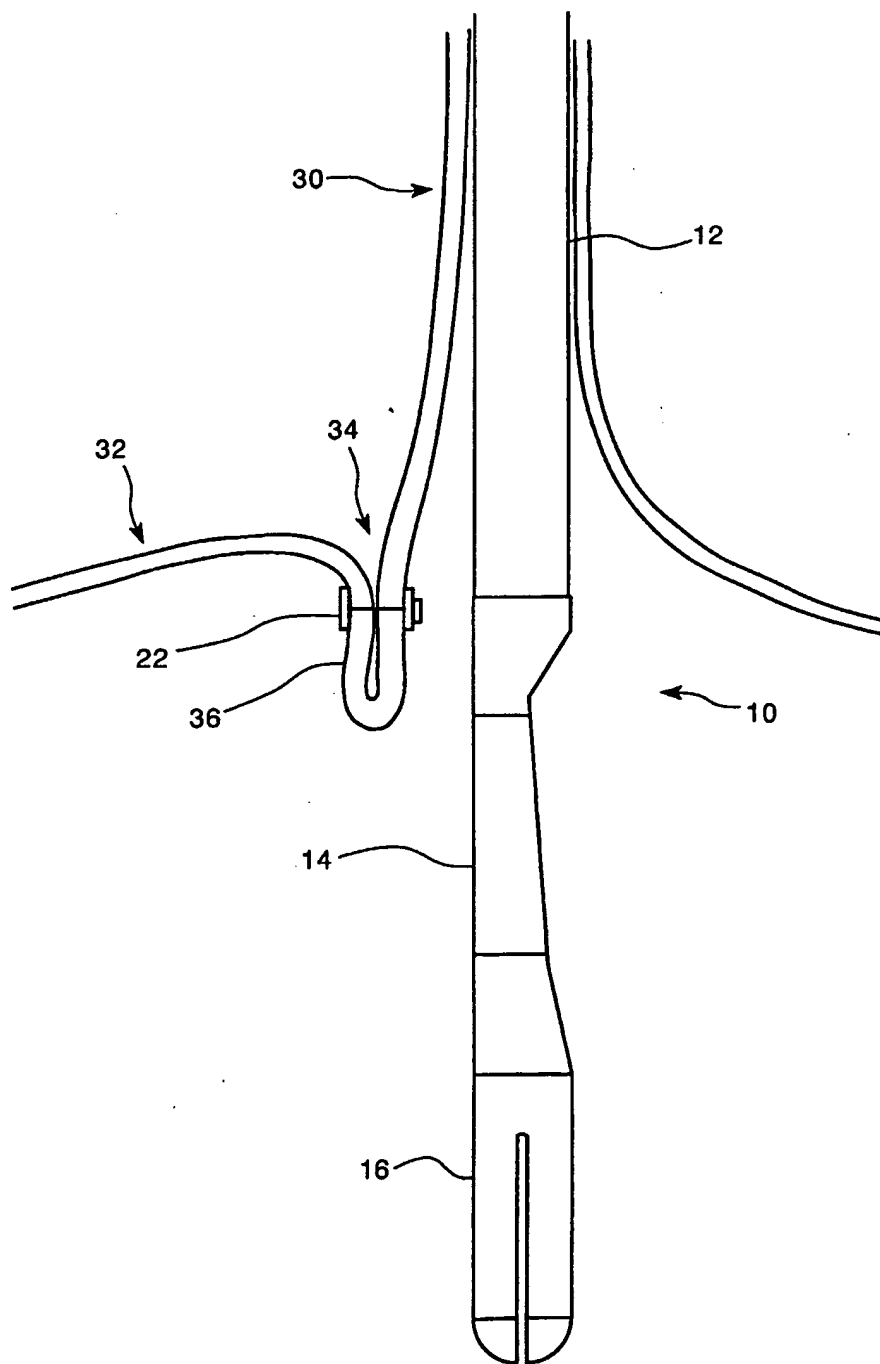


FIG. 8



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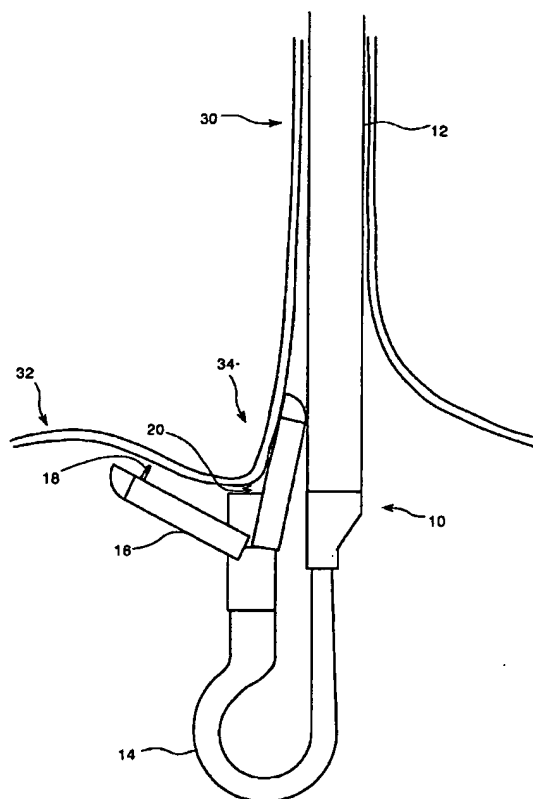
CA 94025 (US). **CERIER, Jeffrey, C.** [US/US]; 11 Orchard Street, Franklin, MA 02038 (US). **CRUZ, Amos** [US/US]; 25 Vine Street, Franklin, MA 02038 (US). **O'KEEFE, Jonathan** [US/US]; 33 Damon Road #1, Scituate, MA 02066 (US). **ANDREWS, Richard** [US/US]; 882 Lower River Road, Lincoln, RI (US). **CHUTTANI, Ram** [IN/US]; 40 Draper Road, Dover, MA 02030 (US). **PIUCCI, Vincent, A.** [US/US]; 51 Thompson Pond Road, Spencer, MA 01562 (US). **BARENBOYM, Michael** [US/US]; 325 Captain Ames Cir., Ashland, MA 01701 (US). **MARSHALL, Neal, H.** [US/US]; 215 Long Hill Road, Bolton, MA 01740 (US). **CHINNOCK, Randal, B.** [US/US]; 53 McGilpin Road, Sturbridge, MA 01566 (US).

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(54) Title: **METHODS AND DEVICES FOR TISSUE RECONFIGURATION**



(57) Abstract: A method includes advancing an apparatus (10) including an elongated member (12) transorally into the stomach. The apparatus (10) includes a distal end effector (15) having first and second members (16) configured to engage tissue. The first and second members (16) are movable relatively toward one another generally in a first plane. The method includes moving the distal end effector relative to the elongated member (12) in the first plane such that the distal end effector is retroflexed out of alignment with the elongated member (16) to position the first and second members (16) for engagement with the tissue. At least one of the first and second members (16) carries a fixation device (22) for fixing engaged portions of tissue together.

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B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

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Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
NONEElectronic data base consulted during the international search (name of data base and, where practicable, search terms used)
NONE**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,088,979 A (FILIPPI et al) 18 February 1992, see entire document.	1-5
A	US 5,674,230 A (TOVEY et al) 07 October 1997, see entire document.	1-5

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
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